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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/628,387 | 08/01/00 | SOON-SHIONG | P ABI1150-18 |

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| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/628,387 | SOON-SHIONG ET AL. | |
| | Examiner | Art Unit | |
| | Amy E Pulliam | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 August 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-171* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-171* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the drug docetaxel is not mentioned in the specification.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-171 are rejected under the judicially created doctrine of double patenting over claims 1-57 of U. S. Patent No. 6,096,331 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming

common subject matter, as follows: a unit dosage form comprising a taxane for systemic administration.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122,125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-78 of copending Application No. 09/628,389. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a unit dosage form comprising a taxane for systemic adminstration.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-171 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dissolved biologic enclosed within a polymeric shell, does not reasonably provide enablement for a unit dosage form comprising a vessel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (CAFC 1988), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to practice the invention as claimed, the skilled artisan would have to produce a unit dosage form comprising a vessel wherein the vessel is not a polymer shell. In doing so, the skilled artisan would have to conduct an unpredictable amount of experimentation for the reasons presented below.

(b) The specification does not teach a unit dosage form comprising a vessel wherein the vessel is not a polymer shell. This limitation appears to be crucial to Applicant's invention (see page 18, line 17 through page 19, line 31).

(c) A working example of the invention wherein the vessel is not a polymer shell is not provided.

(d) The nature of the invention, a unit dosage form comprising a vessel wherein the vessel is not a polymeric shell, is complex.

(e & f) The prior art regarding administration of water insoluble drugs focus on coating the drug or dissolving the drug in an oil phase. See Background of the Invention, Martin et al. (US 4,344,934).

(g) The claims are broad because there is no guidance for a unit dosage form comprising a vessel wherein the vessel is not a polymer shell.

(h) The level of skill in the art of those making a unit dosage form comprising a vessel, wherein the vessel is not a polymeric shell, is high.

The skilled practitioner would first turn to the specification for guidance in making a unit dosage form comprising a vessel wherein the vessel is not a polymer shell. However, the specification does not provide sufficient guidance to the full scope of said method. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not make unit dosage forms comprising a vessel wherein the vessel is not a polymeric shell. Finally, said practitioner would turn to trial and error experimentation to practice the full scope of making a dosage form comprising a vessel wherein the vessel is not a polymeric shell, without guidance from the specification or

the prior art as to which embodiments of the claim are operative. Therefore, undue experimentation becomes the burden of the practitioner.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 are rejected under 35 U.S.C. 102(b) as being anticipated by page 3553 of Drug Facts and Comparisons. This reference teaches that on December 29, 1992, the FDA approved paclitaxel for treatment. Further, the reference shows that the formulations which were approved are 135 $mg/m^2$ or 175 $mg/m^2$, administered intravenously over three hours every three weeks. This disclosure directly anticipates applicants claimed formulations and methods.

Claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, 163, 167, 169, and 171 are rejected under 35 U.S.C. 102(b) as being anticipated by page 3558 of Drug Facts and Comparisons. This

reference teaches that on May 14, 1996 the FDA approved docetaxel for treatment. Further, the reference shows that the formulations which were approved are 60 mg/m$^2$ to 100 mg/m$^2$, administered intravenously over an hour every three weeks. This disclosure directly anticipates applicants claimed formulations and methods.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, and 137-141 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,683,715 to Boni *et al.*. Boni *et al.* disclose taxane formulations useful in the treatment of cancers. More specifically, Boni *et al.* teach of paclitaxel in a formulation for administration to an animal, preferably a human, wherein the animal is afflicted with a cancer and the composition comprises an anticancer effective amount of paclitaxel (c 11-12, claims 1-13). Boni *et al.* further teach that the anticancer effective amount of paclitaxel is from about 1 mg/kg to 500 mg/kg (c 12, claim 14). The above stated claims are composition claims, and Boni *et al.* teaches applicant's claimed drug for treatment of cancer, therefore, anticipating applicant's composition claims.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153-154, 156-158, 160-162, 164-168, and 170 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,648,090 to Rahman. Rahman teaches formulations of taxol (paclitaxel). More specifically, Raqhman teaches that taxol and its derivatives can be used to treat any form of mammalian cancer (c 8, l 5-10). Further, Rahman teaches that the taxol formulations of

his invention are generally administered intravenously to the mammal, in the amount of 50-250 mg active compound/ $m^2$ of the mammalian host (c 8, l 12-21). Therefore, Rahman anticipated the above listed claims because he teaches the composition, method of treatment, and the method of administration.

***Claim Rejections - 35 USC § 103***

Claims 1-171 rejected under 35 U.S.C. 103(a) as being unpatentable over page 3553 or page 3558 of Drug Facts and Comparisons as applied above. The reference does not specifically state the mg amounts as claimed by applicant in claims 58 –78. However, the reference does teach the same concentration amounts, thereby implying that the dosages contain the same amounts, especially as they are used for the same purpose, over the same period of time. One of ordinary skill in the art would have been motivated to make a pharmaceutical formulation of a taxane, either paclitaxel or docetaxel, based on the disclosure in Drug Facts and Comparisons, as the formulations claimed by applicant are taught in the reference for each of these drugs. The expected result would be a successful antitumor formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153-154, 156-158, 160-162, 164-168, and 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boni *et al.* as

applied in the 35 U.S.C. 102(e) rejection above. Boni *et al.* is discussed above as teaching a pharmaceutical formulation for the treatment of an animal, comprising the drug paclitaxel. Boni *et al.* does not specifically teach applicant's claimed method. However, is it the position of the examiner that based on Boni *et al.*'s teaching to administer paclitaxel for the treatment of cancer, the specifics of this method are manipulatable parameters which would be obvious to vary to one of skill in the art, depending on the type of cancer, the size and weight of the patient, the severity of the illness, and the health of the patient. One of ordinary skill in the art would have been motivated to vary the method of administration based on these characteristics. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153-154, 156-158, 160-162, 164-168, and 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,648,090 to Rahman as applied in the above 35 UI.S.C. 102(e) rejection. Rahman is discussed above as teaching the composition and method as claimed by applicant. Rahman does not teach all of the specific parameters in applicant's claimed method claims. However, is it the position of the examiner that based on Rahman's teaching to administer taxol for the treatment of cancer, the specifics of this method are manipulatable parameters which would be obvious to vary to one of skill in the art, depending on the type of cancer, the size and weight of the patient, the severity of the

illness, and the health of the patient. One of ordinary skill in the art would have been motivated to vary the method of administration based on these characteristics. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boni *et al.* or Rahman as applied above, and further in view of US Patent 5,977,163 to Li *et al.*. Boni *et al.* and Rahman are discussed above as teaching applicant's composition and method comprising paclitaxel. However, neither Boni *et al.* nor Rahman disclose the use of docetaxel as the antitumor agent. Li *et al.* is relied upon for the teaching that it is known in the art that docetaxel and paclitaxel are both well known anticancer agents, and can b used interchangeably in antitumor formulations (c 20, claim 1). One of ordinary skill in the art would have been motivated to use any well known antitumor agent in the formulations disclosed by Boni *et al.* or Rahman *et al.*, as both references disclose formulations for the treatment of cancer. One of ordinary skill in the art would expect another well known cancer agent to have the same effects as paclitaxel. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
January 26, 2001

THURMAN K. PAGE
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